510(K) SUMMARY of SAFETY and EFFECTIVENESS

K073300

This summary of 5l0(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Device Act (SMDA) of l990 and 21 CFR §807.92.

The assigned 5l0(k) number is:_____.

1. Submitter's Identification:

Milesman, S.L.
Max Planck 545, P.I. Roces,
33211 Gijon,
Asturias, Spain

DEC 0 4 2007

Date Summary Prepared: August 15, 2007

2. Name of the Device:

Trade Name: Milesman Premium Pulsed Diode Array Laser System

Classification Name: Laser Instrument, Surgical, Powered
21CFR Part 878.4810
Product Code: GEX
Review Panel: General & Plastic Surgery

3. Predicate Device Information:

K#003614, LightSheer™ Pulsed Diode Array Laser System

4. Device Description:

The Milseman Premium Pulsed Diode Array Laser System delivers pulsed laser light at 800 nm wavelength. The device consists of three interconnected sections: the system console, the handle hose (umbilical cord) to the handpiece, and the handpiece. The laser pulsed energy is delivered through the handpiece. A user is able to select specific laser parameters from the touch screen on top of the console.

5. Intended Use:

The Milesman Premium Pulsed Diode Array Laser System is intended for use in general and plastic surgery and dermatology procedures for the treatment of vascular lesions, such as angiomas, hemangiomas, telangiectasia and other benign vascular lesions and treatment for pseudofolliculitis barbae.

The Milesman Premium is also used for removal of unwanted hair, permanent hair reduction and the treatment of benign pigmented lesions and leg veins in all skin types (Fitzpatrick I-VI), including tanned skin.

6. Comparison to Predicate Device:

The Milesman Premium and the LightSheer ET are very similar or identical in terms of the device structure and its technology. Both systems are medical laser devices that deliver intense pulsed light at 800nm and are designed for effective photothermolysis treatment of soft tissue in general and plastic surgery, i.e. benign pigmented lesions, vascular lesions, leg veins, and removal of unwanted hair and permanent hair reduction.

The main differences between the Milesman Premium and LightSheer™ devices are in the refrigeration systems and in the number of diode lasers. The Milesman Premium and predicate LightSheer™ ET use different methods for obtaining the refrigeration with Milesman Premium refrigeration based on refrigeration by compression which is more efficient than thermoelectric refrigeration used by the predicate device. The diode laser array of Milesman Premium is formed by 2 matrixes of 10 the bars. The LightSheer™ ET diode array is formed by 2 matrixes of 35 bars. Due to a different method of bars assembly, the Milesman Premium is able to deliver the same amount of energy as LightSheer™ while using fewer diode lasers.

The above features of Milesman Premium do not introduce any new questions regarding the safety and effectiveness of the device.

7. Performance Data:

The Milseman Premium Pulsed Diode Array Laser System and the predicate LightSheer™ Pulsed Diode Array Laser System have very similar specifications and indications for use and as such, the performance data are not required.

8. Discussion of Clinical Tests Performed:

Non-Applicable

9. Conclusion:

The Milseman Premium Pulsed Diode Array Laser System has the same intended use and similar characteristics as the LightSheer™ Pulsed Diode Array Laser System. Moreover, documentation supplied in this submission demonstrates that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the Milesman Premium System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 4 2007

Milesman, S.L.
% Intertek Testing Services
Mr. Daniel W. Lehtonen
2307 East Aurora Road, Unit B7
Twinsburg, Ohio 44087

Re: K073300
Trade/Device Name: Milesman Premium Pulsed Diode Array Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general, and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: November 21, 2007
Received: November 23, 2007

Dear Mr. Lehtonen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K073300

Device Name **Milesman Premium Pulsed Diode Array Laser System**

The Milesman Premium Pulsed Diode Array Laser System is intended for use in general and plastic surgery and dermatology procedures for the treatment of vascular lesions, such as angiomas, hemangiomas, telangiectasia and other benign vascular lesions and treatment for pseudofolliculitis barbae.

The Milesman Premium is also used for removal of unwanted hair, permanent hair reduction and the treatment of benign pigmented lesions and leg veins in all skin types (Fitzpatrick I-VI), including tanned skin.

Prescription Use X		**Over-The Counter Use** _____
(Per 21 CFR 801 Subpart D)	**OR**	**(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K073300